K121855

AUG 16 2012

510(k) SUMMARY

Submitter:
Stryker Sustainability Solutions
1810 W Drake Dr
Tempe, Arizona 85283

Contact:
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Date of preparation: 21 June 2012

Name of device:

Trade/Proprietary Name:	Reprocessed SERFAS Energy Probe
Regulation Name:	Electrosurgical, Cutting & Coagulation Accessories, Laparoscopic & Endoscopic, Reprocessed
Regulation Number:	21 CFR 878.4400
Regulatory Class:	Class II
Product Code:	NUJ

Predicate Device:

Predicate Device	510(k) Title	Manufacturer
K041810	IMPULSE Energy System	Stryker Endoscopy
K991960	SERFAS Energy System	Stryker Endoscopy

Device Description:
The Reprocessed SERFAS Energy Probe includes an energy-transferring cable as well as several different tip configurations and suction probes which are capable of providing simultaneous fluid aspirations.

Indications for Use:
The Reprocessed SERFAS Energy Probe is a disposable, radio-frequency probe used in electrosurgical procedures for resection, ablation, and coagulation of soft tissue, as well as the hemostasis of blood vessels in patients undergoing arthroscopic surgery for the knee, shoulder, ankle, hip, elbow and wrist.

Technological Characteristics:

The design, materials, and intended use of Reprocessed SERFAS Energy Probe are identical to the predicate devices. The mechanism of action of the Reprocessed SERFAS Energy Probe is identical to the predicate devices in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of SERFAS Energy Probes includes removal of adherent visible soil and decontamination. Each individual Probe is tested for appropriate function of its components prior to packaging and labeling operations. components prior to packaging and labeling operations.

Performance data:
Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed SERFAS Energy Probes. This included the following tests:

- Biocompatibility
- Validation of reprocessing
- Sterilization Validation
- Function test(s)
- Packaging Validation

Performance testing demonstrates that Reprocessed SERFAS Energy Probes perform as originally intended.

Conclusion:
Stryker Sustainability Solutions concludes that the modified devices (Reprocessed SERFAS Energy Probes) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Sustainability Solutions
% Mr. Eric Varty
Vice President
1810 West Drake Drive
Tempe, Arizona 85283

AUG 16 2012

Re: K121855
Trade/Device Name: Reprocessed SERFAS Energy Probe
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accesories
Regulatory Class: Class II
Product Code: NUJ
Dated: June 21, 2012
Received: June 25, 2012

Dear Mr. Varty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121855

Device Name: Reprocessed SERFAS Energy Probe

Indications For Use: The Reprocessed SERFAS Energy Probe is a disposable, radio-frequency probe used in electrosurgical procedures for resection, ablation, and coagulation of soft tissue, as well as the hemostasis of blood vessels in patients undergoing arthroscopic surgery for the knee, shoulder, ankle, hip, elbow and wrist.

Prescription Use: __X____ AND/OR Over-The-Counter Use:_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121855